Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Bacillus thuringiensis* subsp. *israelensis

Serotype H14, Strain SA3A

Product type: PT18

ECHA/BPC/018/2014

Adopted

19 June 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain SA3A for product type 18

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 18 of the following active substance:

Common name:	***Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain SA3A**
Chemical name(s):	**not applicable**
EC No.:	**not applicable**
CAS No.:	**not applicable**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Sumitomo Chemical Agro Europe SAS (for Valent BioSciences Corporation) on 30 April 2006, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 12 June 2009. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member of Italy

The BPC opinion on the approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain SA3A in product type 18 was adopted on 19 June 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain SA3A (hereafter *Bti* SA3A) in product type 18 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain SA3A in product type 18. *Bti* SA3A is a Gram positive, spore forming rod-shaped bacterium that produces a crystalline protein inclusion which is toxic to larvae of some dipteran insects. *Bti* SA3A originates from a natural wild strain of the bacteria and has not been genetically modified nor is it the result of a spontaneous or an induced mutation. *Bti* is a common naturally occurring microorganism with worldwide distribution. The species has been detected both in soil and on insects and plants and could be indigenous to intended areas of application.

The crystals produced by *Bti* SA3A are taken up by the target insect larvae via ingestion. Under the alkali conditions present in the larvae gut and the activity of gut proteases the crystal dissolves releasing the active protein δ-endotoxins that induce disintegration of the gut epithelium and consequent death of the larvae. Quality control of the fermentation slury ensures that no toxins relevant for human health are present. Specifications for the reference strain are established.

The biological, physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product. Genetic stability is ensured through manufacturing directions for the fermentation process.

Adequate methodology exists for the identification of *Bti* SA3A at strain level.

The classification and labelling for *Bti* SA3A according to Regulation (EC) No 1272/2008 (CLP Regulation) is not required as the active substance is a living micro-organism not covered under the Regulation. It is not biohazardous according to Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work[1]. However, based on the precautionary principle, all microorganisms should be consideredto have the potential to provoke sensitising reactions.

b) Intended use, target species and effectiveness

Bti SA3A is a biological insecticide in product type 18 intended for both professional and non-professional uses. The use of *Bti* SA3A is for the control of mosquito and black fly larvae in aquatic breeding habitats and filter fly midges in sewage treatment plants.

[1] OJ L 262, 17.10.2000 p.21

Bti SA3A as formulated in the representative biocidal product, ` is not intended for use in irrigation systems except for flood (basin), irrigation systems or in water intended for direct human uses. It is not intended to be used on clean purified drinking water.

Bti SA3A is specific to larvae of certain dipteran insect species. Consequently, the timing of application will depend on the level of larvae infestation and growth stage. The product should be applied during the first to the early 4th larval instar, since during the later part of the 4th instar growth stage the larvae are no longer eating and the product will not be effective. Treatment is restricted to a maximum of 5 treatments per season.

Bti SA3A is applied using conventional ground application equipment, with quantities of water sufficient to provide uniform coverage of the target area. *Bti* SA3A as formulated in the representative biocidal product is first added to water to prepare a final spray mixture for use at rates up to 1000 L/ha.

The data on *Bti*SA3A and the representative biocidal product have demonstrated sufficient efficacy against the target species.

In the laboratory, resistance to individual toxins of *Bti* has been observed for several insects. However, significant resistance to whole cultures of *Bti* has not been achieved. Cross resistance between *Bacillus thuringiensis* toxins has been found under laboratory conditions. Resistance in the field to *Bti* has not been documented.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Bti SA3A indicates no evidence of infectivity or pathogenicity in relation to human health, no adverse effects in humans is expected. Data show that there are no adverse effects following actual exposure of humans nor in the available data and therefore an AEL for the active substance is not considered necessary. Safety considerations are limited to the sensitizing potential relevant for all microorganisms.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Mixing and loading	primary, qualitative assessment and simulations	Professionals and non-professionals
Spraying	primary, qualitative assessment and simulations	Professionals
Home garden sprayer	primary, qualitative assessment and simulations	non-professionals
Bystanders	secondary, qualitative assessment	General public

A qualitative risk assessment was undertaken as due to the lack of adverse effect no AEL was derived. A quantitative exposure assessment based on simulations showed that the exposures are negligible for both professionals and non-professional users without the use of PPE. No unacceptable risks were identified for professionals for all scenarios.

However, as microorganisms may cause sensitization reactions, the use of personel protective equipment (PPE) is needed. Professionals are recommended to wear a dust mask to reduce inhalation exposure during mixing/loading and during application, except if enclosed tractor cabs are used. Only users wearing PPE are permitted in areas being treated.

No unacceptable risks were identified for non-professional users for systemic effects. As *Bti* SA3A is a micro-organisms it may have the potential to provoke sensitization reactions therefore risk mitigation measures e.g. using water soluble packaging must be considered to reduce contact.
No unacceptable risks were identified for bystanders.

Environment

Bacillus thuringiensis (Bt) has been isolated worldwide from a range of habitats. *Bti* vegetative cells and insecticidal toxins of *Bti* have a limited survival time in the environment and the spores do not germinate readily, making it unlikely that *Bti* SA3A will multiply and colonize areas of intended use above levels that may occur naturally.

Bti SA3A exhibits specific toxicity to dipteran insect larvae, has a very limited impact on non-target organisms and is non-toxic to mammalian species. Bt species are not infective within populations of the target organism and re-infection in the field after application is not expected. Bt species can be considered a natural part of the microbiota on plant surfaces and are not translocated within plants.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Direct application to water	1-5 repetitions at a minimum interval of 7 days. No adsorption and interceptions are assumed, and first order degradation rates for spores and toxin between applications.

No unacceptable risks were identified for surface water.. Adverse effect on the microbial activity occurring in sewage treatment plants as a result of use of *Bti* SA3A is not expected.

2.2. Exclusion, substitution and POP criteria

For microorganisms the assessment of exclusion criteria is not relevant. The assessment of substitution criteria is relevant for micro-organisms. It has been agreed that substitution criteria are assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" agreed at the 54th meeting of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the substitution criteria is based on Article 10(1)(a, b and d). Of these Article 10(1)(b) may be relevant although micro-organisms are not covered by CLP. All microorganisms are considered as potential sensitizers. In

the absence of data indicating respiratory sensitization *Bti* SA3A does not meet Article 10 (1b). The other criteria (Article 10(1)(a and b) are not applicable for microorganisms.

Therefore, *Bti* SA3A does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

For microorganisms the assessment of POP criteria is not relevant.

2.3. BPC opinion on the application for approval of the active substance *Bti* SA3A in product type 18

In view of the conclusions of the evaluation, it is proposed that *Bti* SA3A shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: Bacillus thuringiensis subsp. israelensis Serotype H14, Strain SA3A and "no relevant impurities".
2. The product assessment shall pay particular attention to the exposure, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed at the Union level risk assessment of the active substance.
3. For professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
4. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[2] or Regulation (EC) No 396/2005[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

As all microorganisms are considered as potential sensitizers, based on the precautionary principle, the active substance may not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

1. Considering that all microbials should be regarded as potential sensitisers, the agreed warning phrase on the product label is "Microorganisms may have the potential to provoke sensitising reactions".
2. The possibility of sensitisation to (non)-professionals from products containing *Bti* SA3A should be addressed by a qualitative risk assessment covering all routes of potential exposure at product authorisation since the active substance is a microorganism which may cause sensitization reactions. Products for non-professionals shall normally not be authorised if the wearing of PPE/RPE is the only mitigation measure to reduce exposure to acceptable level. Other elements leading to a reduction of exposure like pack size and design should be considered.
3. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1

application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

4. Due to the lack of certainty regarding exposure and risk to human gastroenteritis from potentiall expression of Bacillus cereus toxins a labelling provision like keep away from food to cover potential hazards should be considered.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of *Bti* SA3A.

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